

Application No. 10/780,103
Amendment Dated January 5, 2005
Reply to Office Action of October 5, 2004

REMARKS

In the Office Action dated October 5, 2004, claims 49-88 were examined with the result that all claims were rejected. In response, Applicant has rewritten claims 49, 59, 69 and 79, and canceled claims 50-53, 60-63, 70-73 and 80-83. In view of the above amendments and following remarks, reconsideration of this application is requested.

In the Office Action, claims 49-88 were rejected under 35 USC §112, first paragraph, as being non-enabling. The Examiner rejected the claims as having insufficient guidance to teach one skilled in the art how to use the invention successfully for the treatment of a broad range of "cancerous diseases." In response, Applicant has limited the term "cancerous disease" by specifying leukemia, colon cancer, breast cancer, and prostate cancer as the type of diseases to which the compounds are directed. Applicant believes that the specification as filed adequately supports such uses.

More particularly, Applicant has provided HL-60 cell differentiation data on the four compounds disclosed and claimed. HL-60 cells are human leukemia cells, and induction of differentiation of HL-60 promyelocytes to monocytes is an accepted model for evidencing use against those four cancerous diseases. As the four independent claims have now been amended to be limited to such diseases, Applicant believes the Examiner should withdraw the §112, first paragraph rejection of original claims 49-88.

In the Office Action, the Examiner also rejected claims 49-58 under the judicially created Doctrine of Obviousness Type Double Patenting as being unpatentable over claims 12-22 of copending Application No. 10/690,990. However, Applicant believes the Examiner is actually referring to Application No. 10/669,990 and not Application No. 10/690,990. Applicant does not have such a serial number identifying any of its vitamin D applications, and therefore, Applicant believes the Examiner's recitation of the application number found at page 6, fourth last line in the Office Action of October 5, 2004, is a typographical error. Accordingly, Applicant will direct its comments to Application No. 10/669,990.

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In Application No. 10/669,990, the vitamin D compound is 2-methylene-19-nor-20(S)-1 α ,25-dihydroxyvitamin D₃ (referred to as 2MD). This compound and its biological activity is disclosed in U.S. Patent 5,843,928 issued December 1, 1998. As can be seen from the '928 patent, especially from the data in Table 1, and the description at column 15, line 63 through column 16, line 11, the compound 2MD has bone calcium mobilization activity that is greater than 1 α ,25-dihydroxyvitamin D₃, but has intestinal calcium transport activity which is less than 1 α ,25-dihydroxyvitamin D₃. In contrast, the compound 20(S)-1 α ,25-dihydroxyvitamin-2-methylene-26,27-dihomo-19-nor-vitamin D₃ covered by the method of claims 49-58, has both bone calcium mobilization activity and intestinal calcium transport activity that is greater than 1 α ,25-dihydroxyvitamin D₃. Applicant refers the Examiner to the data contained in Table 4 found at the bottom of page 28 of the present specification. These data clearly illustrate that the 26,27-dihomo compound claimed in claims 49-58 has different and unexpected calcemic activity from the compound 2MD.

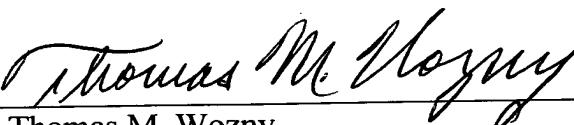
Accordingly, Applicant believes the Examiner should withdraw the obviousness type double patenting rejection of claims 49-58.

An effort has been made to place this application in condition for allowance and such action is earnestly requested.

Respectfully submitted,

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